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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/980,062
Filing Date: May 10, 2002
Appellant(s): NAIDU, A SATYANARAYAN

Paul D. Chancellor
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 9, 2006 appealing from the Office action mailed April 7, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 2, 19, and 103 under 35 U.S.C. 102(b) over the WO Patent Application 91/13982 is withdrawn because these claims have been amended to delete lipids from the list of possible substrates. The WO Patent Application '982 is still applied against other claims, and claims 2, 19, and 103 remain rejected under 35 U.S.C.

102(b) and 35 U.S.C. 102(e) over other references, as indicated in Appellants' statement of the grounds of rejection.

GROUNDS OF REJECTION NOT ON REVIEW

The following grounds of rejection have not been withdrawn by the examiner, but they are not under review on appeal because they have not been presented for review in the appellant's brief. The rejection of claims 86 and 120-122 under 35 U.S.C. 112, second paragraph, set forth in section 3 of the final Office action mailed April 7, 2005 is not discussed in Appellants' Brief.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 6,475,511	Gohlke et al	11-2002
US 6,066,469	Kruzel et al	05-2000
EP 753,308	Gambit Intl. Ltd. Tortola	01-1997
EP 753,309	Gambit Intl. Ltd. Tortola	01-1997
WO 91/13982	Ferrodynamics, Inc.	09-1991

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

Claims 86 and 120-122 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the

composition" at claim 86, line 2. Note that at line 1 of the claim, "composition" was changed to "foodstuff". There is no antecedent basis in the claims for the phrase "the cosmetic, cleanser, food supplement, or medicament" in claim 120. It is believed that claim 120 should instead depend upon claim 119.

Claim Rejections - 35 USC § 102/103

Claims 1, 11, 18, 28, 31, 38, 39, 101, 102, 119-124, 126-129, 131, 132, 134, 142-148, 197, and 200 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 91/13982. The WO Patent Application '982 teaches lactoferrin in combination with stearic acid (which is a lipid and also corresponds to Applicant's pharmaceutically acceptable carrier of claim 102) or its salts. The composition is used as an antiseptic. Lactoferrin concentrations on the surfaces to be treated are 0.1-1 mg/6 cm^2 (approximately equal to 0.1-1 mg/in^2). Buffers can be present in the antiseptic compositions of the reference. See, e.g., page 7, line 30 - page 9, line 24. Because the same components are present in the same defined dispersion, inherently the lactoferrin in the composition of the WO Patent Application '982 will be immobilized via its N-terminus to the stearic acid to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the composition of the WO Patent Application '982 and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the composition of the WO Patent Application '982. With respect to instant claims 101, 122-124, 126-129, 131, 132, 134, and 142-148, note that an intended use limitation does not impart patentability to composition claims where the composition is otherwise anticipated by or obvious over the prior

art, and that these claims do not structurally or functionally limit the claimed compositions so as to distinguish over those taught by the WO Patent Application '982.

Claims 149-151, 153, 164, 171-173, 175, 186, and 193-195 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 91/13982. Application of the WO Patent Application '982 is the same as in the above rejection of claims 1, 11, 18, 28, 31, 38, 39, 101, 102, 119-124, 126-129, 131, 132, 134, 142-148, 197, and 200. The WO Patent Application '982 teaches administering its antiseptics to mammals, but does not particularly teach treating humans or non-human vertebrates. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the antiseptic compositions of the WO Patent Application '982 to treat both human and non-human mammals because it is desirable to treat both human and non-human mammals with antiseptics and because the activity of the antiseptic compositions of the WO Patent Application '982 would not have been expected to be affected by the subject being treated, but rather would have been expected to have general utility regardless of where the source of microbial contamination is found.

Claims 1, 2, 5, 18, 19, 22, 31, 101-103, 106, 115-117, 119-124, 126-129, 131-132, 134, 136, 142-151, 153, 164, 171-173, 175, 186, 193-197, and 200-202 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 753,309. The European Patent Application '309 teaches compositions comprising lactoferrin and carriers such as paraffin oil and Vaseline (which are lipids), xantan gum and corn starch (which are polysaccharides), and lecithin (which is an emulsifier). The compositions are in the form of ointments, creams, gels, and powders The compositions are used to prevent or treat viral infections on the skin or mucosae of humans or animals. See, e.g., the Abstract; Examples 5-8; and claim 1. Because the

same components are present in the same defined dispersion, inherently the lactoferrin in the composition of the European Patent Application '309 will be immobilized via its N-terminus to the paraffin oil, Vaseline, xantan gum, and corn starch to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the composition of the European Patent Application '309 and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the composition of the European Patent Application '309. With respect to instant claim 101, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by or obvious over the prior art.

Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 753,309. Application of the European Patent Application '309 is the same as in the above rejection of claims 1, 2, 5, 18, 19, 22, 31, 101-103, 106, 115-117, 119-124, 126-129, 131-132, 134, 136, 142-151, 153, 164, 171-173, 175, 186, 193-197, and 200-202. The European Patent Application '309 does not teach a lactoferrin/surface area ratio for the surfaces to be treated. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal doses for the lactoferrin-containing compositions of the European Patent Application '309 because dose is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

Claims 1, 2, 5, 18, 19, 22, 31, 32, 101-103, 106, 115, 119-124, 126-129, 131-136, 142-151, 153, 159, 162-165, 171-173, 175, 181, 184-187, 193-197, and 200-202 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 753,308. The

European Patent Application '308 teaches compositions comprising lactoferrin and peppermint oil, gum base and corn starch (which are polysaccharides), glucose, and additional antibiotic compounds such as erytromicin and ampicillin. The compositions are in the form of gargles, aqueous solutions, chewing gum, and powders The compositions are used to prevent or treat bacterial infections such as by S. aureus and S. pyogenes on the skin or mucosae of humans or animals. See, e.g., the Abstract; Examples 5-8; and the claims. Because the same components are present in the same defined dispersion, inherently the lactoferrin in the composition of the European Patent Application '308 will be immobilized via its N-terminus to the peppermint oil, gum base, and corn starch to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the composition of the European Patent Application '308 and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the composition of the European Patent Application '308. With respect to instant claim 101, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by or obvious over the prior art.

Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 753,308. Application of the European Patent Application '308 is the same as in the above rejection of claims 1, 2, 5, 18, 19, 22, 31, 32, 101-103, 106, 115, 119-124, 126-129, 131-136, 142-151, 153, 159, 162-165, 171-173, 175, 181, 184-187, 193-197, and 200-202. The European Patent Application '308 does not teach a lactoferrin/surface area ratio for the surfaces to be treated. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal doses for the

lactoferrin-containing compositions of the European Patent Application '308 because dose is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

Claims 1-3, 5, 18-20, 22, 31, 32, 102-104, 106, 115, 119, 124, 137, 138, 142-150, 154, 164, and 165 are rejected under 35 U.S.C. 102(e) as being anticipated by Kruzel et al (U.S. Patent No. 6,066,469). Kruzel et al teach nutritional supplements comprising lactoferrin in combination with adjuvants or diluents such as cellulose, starch, gelatin, tragacanth, and sodium carboxymethylcellulose. Lactoferrin acts to treat or prevent bacterial, viral, and fungal infections, such as S. pneumoniae infections. See, e.g., column 6, lines 40-56, and column 8, line 47 - column 9, line 7. Because the same components are present in the same defined dispersion, inherently the lactoferrin in the nutritional supplements of Kruzel et al will be immobilized via its N-terminus to the carriers or diluents to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the compositions of Kruzel et al and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the compositions of Kruzel et al. With respect to instant claims 144-148, an intended use does not impart patentability to composition claims where the composition is otherwise anticipated by or obvious over the prior art.

Claims 102-104, 115-117, 119, 124, 127, 128, 137, 138, 142-148, 154, 157, 158, 171, 172, 176, 179, 180, 186, and 193-196 are rejected under 35 U.S.C. 102(e) as being anticipated by Gohlke et al (U.S. Patent No. 6,475,511). Gohlke et al teach lactoferrin combined with colostrum (which inherently contains proteins such as casein, polysaccharides, lipids, lactose,

cholesterol, physiological emulsifiers, monoglycerides, and diglycerides), pectin (which is a polysaccharide), and pharmaceutically acceptable carriers such as dextrose (see, e.g., Examples 1-3). The components are thoroughly mixed and cold pressed to form a lozenge. The lozenges are administered to the oral mucosa, whereby the lactoferrin is absorbed and enters the bloodstream and inhibits infections in mammals, especially humans (see, e.g., the abstract). Because the same components are present in the same compositions, inherently the lactoferrin in the lozenges of Gohlke et al will be immobilized via its N-terminus to the proteins, polysaccharides, and lipids which are present to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the compositions of Gohlke et al and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the compositions of Gohlke et al. With respect to instant claims 142-148, an intended use does not impart patentability to composition claims where the composition is otherwise anticipated by or obvious over the prior art.

Gohlke et al is available as prior art against instant claims 102-104, 115-117, 119, 124, 127, 128, 137, 138, 142-148, 154, 157, 158, 171, 172, 176, 179, 180, 186, and 193-196 because these claims are not entitled under 35 U.S.C. 120 to the benefit of the filing date of grandparent application 09/322,700. These claims are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the grandparent application '700 because the grandparent application '700, under the test of 35 U.S.C. 112, first paragraph, does not disclose pharmaceutically acceptable carriers, does not disclose systemic administration, does not disclose administration through a transmucosal delivery route, does not disclose ingestive delivery systems such as lozenges, and does not disclose administering to non-human vertebrates in general.

(10) Response to Argument

Appellants present four major arguments in replying to the prior art rejections set forth above. Appellants contend: (1) that the references do not teach immobilizing lactoferrin to a substrate via the N-terminus of the lactoferrin; (2) that mere mixing, compounding, or cold-pressing of ingredients, e.g., as occurs in Gohlke et al, the WO Patent Application '982, and Kruzel et al, is not sufficient to result in immobilization of lactoferrin by N-terminus to a substrate; (3) that the compounds taught by several of the references, i.e. the WO Patent Application '982, the European Patent Application '309, and the European Patent Application '308, and which are alleged in the rejections to correspond to Appellants' claimed substrates, are too small in terms of molecular weight to constitute substrates to which lactoferrin can be immobilized; and (4) that the compounds taught by several of the references, i.e. the European Patent Application '309, the European Patent Application '308, and Kruzel et al, and which are alleged in the rejections to correspond to Appellants' claimed substrates, are not negatively charged such that the positively charged N-terminus of lactoferrin can be immobilized. A declaration by Barron under 37 CFR 1.132, filed August 2, 2004, has been submitted to support these arguments.

With respect to contention (1), the examiner agrees that none of the references describe their compositions in terms of lactoferrin binding via its N-terminus region to a substrate. However, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). The basis for all of the prior art rejections is inherency. Because the prior art

references teach the same components present in the same types of compositions as are claimed by Appellants, a prima facie case of anticipation is established. *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Sufficient evidence of similarity is deemed to be present between the prior art compositions and Appellants' claimed compositions (see the reasons set forth in the particular rejections as set forth above) to establish prima facie anticipation, with the burden thus shifting to Appellants to provide evidence to rebut the prima facie case. *In re Spada,* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The examiner maintains that the Barron declaration is insufficient to rebut the prima facie cases because the declaration is unsupported by evidence including evidence of direct testing of the prior art compositions, and because assertions made in the declaration are unsupported by, and are even contradicted by, statements made in the application as originally filed.

With respect to contention (2), Appellants and Declarant argue that mixing, compounding, and cold pressing as occur in Gohlke et al, the WO Patent Application '982, and Kruzel et al will not provide an environment suitable to cause the lactoferrin to become attached to a substrate via the lactoferrin's N-terminus region. However, Declarant does not provide any reasoning or evidence as to why these processing steps are insufficient to result in immobilization via the N-terminus of lactoferrin. See paragraphs 13, 14, 19, 20, 35, 37, and 38 of the declaration. Further, there is no disclosure anywhere in the specification that special procedures or conditions are necessary in order to achieve the desired immobilization. See, e.g., page 11, lines 3-11, of the specification. In the absence of a disclosed need for special conditions, the prior art references' disclosed thorough mixing and cold pressing of the ingredients in powder form is deemed to be sufficient to result in the claimed immobilization.

Assuming arguendo that a substrate must be negatively charged in order for the N-terminus of lactoferrin to be immobilized (see Appellants' contention (4)), then because the stearic acid of the WO Patent Application '982 has a negatively charged carboxyl group, all that it would take for the positively charged N-terminus of lactoferrin to become immobilized on the negatively charged carboxyl group would be to bring the two opposite charges into close physical proximity - charge attraction will do the remainder of the work. Any pharmaceutical compounding step will provide the necessary physical proximity so that at least some of the lactoferrin is immobilized by its N-terminus to a least some of the stearic acid. Appellants' argument in contention (2) is thus refuted by Appellants' argument in contention (4).

With respect to contention (3), Appellants and Declarant argues that the stearic acid of the WO Patent Application '982; the paraffin oil, vaseline, and lecithin of the European Patent Application '309; and the peppermint oil of the European Patent Application '308; can not serve as substrates because of their low molecular weights. See paragraphs 17, 23, 27, and 30 of the declaration. This argument can not be accepted because it contradicts the original disclosure of substrates with molecular weights significantly less than that of lactoferrin. For example, the originally-filed specification at page 10, lines 19-22, and originally-filed claim 3 recite that lipids, adenosine triphosphate, and triglycerides are all useful and acceptable substrates. These exemplified substrates have molecular weights which are significantly less than that of lactoferrin. Further, Appellants continue to claim substrates (e.g., the nucleotide of claim 2, and the adenosine triphosphate of claim 3) which are of a size that Appellants and Declarant argue are too small to serve as substrates. When arguments made by Appellants or by Declarant contradict those made in the originally-filed application or in the claims, the latter preponderate.

With respect to contention (4), Appellants and Declarant state that "[f]or the N-terminus region to become immobilized on a naturally occurring substrate, the region of the substrate to which the N-terminus region is to become attached should carry the opposite charge, i.e., carry a negative charge." See the declaration at paragraph 9, and also paragraphs 25, 26, 31, and 36. However, Declarant does not provide any citation to the specification which would support this contention, and the examiner can find no support in the original disclosure of the invention for this contention. Further, this argument is inconsistent with the disclosure in the specification of useful substrates which do not have a positive charge. For example, the original specification at page 10, line 22, and originally-filed claim 3 disclose triglycerides to be useful substrates for immobilizing lactoferrin by its N-terminus region. Triglycerides are uncharged. The original specification at page 10, lines 19-22, and originally-filed claim 3 disclose proteins, polysaccharides, and lipids to be useful substrates for immobilizing lactoferrin by its N-terminus. These classes of compounds embrace positively charged, negative charged, and uncharged compounds. To the extent that the opinions set forth in the declaration are contradicted by the specification, they can not be relied upon to rebut the prima facie case of anticipation. Finally, this argument by Declarant uses a significant qualifier "should". Because of the use of this word, Declarant in effect admits that a substrate does not have to have a negative charge in order to be useful in immobilizing lactoferrin by its N-terminus. At page 18 of the Brief, Appellants contend that the word "should" is used by Declarant to express condition, i.e. as a synonym for "must". Appellants cite Merriam-Webster's Collegiate dictionary in support. However, the Dictionary makes clear that "should" can also be used to express expediency (see definition 2) or probability (see definition 4). Appellants have not explained how it is known in which sense

"should" was used by Declarant. The best evidence of which definition of "should" was intended by Declarant would be a statement by Declarant. In the absence of such a statement, the examiner will chose a definition which does not result in a contradiction between the declaration and the disclosure of the invention. Because interpreting "should" to mean "must" would result in a contradiction with the original disclosure of the invention as outlined above, the examiner interprets "should" as meaning expediency or probability. A preference for negatively charged substrates as posited by Declarant does not rebut the prima facie cases of anticipation based upon prior art references which teach the same uncharged substrates originally disclosed by Appellants.

Appellants correctly state at page 16 of the Brief that they are not required to provide an explanation in the specification concerning how the invention works. However, if Appellants choose not to provide an explanation as to how the invention works, then Declarant can not make unsupported statements as to how the invention works. Dr. Barron's explanation that the positive N-terminus region must bind to a negatively charged substrate is unsupported because Appellants never provided any explanation as to how the invention works, and because the explanation asserted by Declarant contradicts circumstances (e.g., immobilization on uncharged triglycerides) which the specification originally disclosed would work. When the application is considered in its entirety, and when originally-filed claim 3 is considered in its specifics (see the last word in the claim), it is clear that it was originally disclosed that lactoferrin can be immobilized by its N-terminus to triglycerides, which are uncharged molecules. The only evidence of record of any inconsistency between Appellants' overall teachings and Appellants'

initial recitation of triglycerides and other lipids is the Barron declaration, and an unsupported opinion declaration does not preponderate over Appellants' original disclosure.

Appellants argue that the obviousness rejections based upon the WO Patent Application 91/13982, the European Patent Application 753,309, the European Patent Application 753,308 stand or fall with the anticipation rejections based upon these references. The examiner agrees.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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